Risk Benefit Analysis

Dr. Vajira H. W. Dissanayake MBBS (Colombo), PhD (Nottingham)
Senior Lecturer, Human Genetics Unit
&
Joint-secretary, Ethics review committee

Faculty of medicine, university of Colombo

Requirements for Evaluating the Ethics of Research

1. Collaborative Partnership
2. Social Value
3. Scientific Validity
4. Fair Subject Selection
5. Favourable Risk Benefit Ratio
6. Independent Review
7. Informed Consent
8. Respect for Research Participants

“Minimal Risk”

1. Research involving no more than minimal risk.

2. Research involving greater than minimal risk,
but presenting the prospect of direct benefit to the individual subjects.

3. Research involving greater than minimal risk and
no prospect of direct benefit to individual subjects,
but likely to yield generalizable knowledge about the subject's disorder or condition.

4. Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of the participants.

“Minimal Risk ?”

For research involving greater than minimal risk

1. the potential risks to individual subjects should be minimized,

2. the potential benefits to individual subjects should be enhanced, and

3. the potential benefits to individual subjects and society should be proportionate to or outweigh the risks.

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“Benefits”

only benefits that accrue to participants from the interventions necessary to achieve the research objectives or those deriving from the knowledge to be gained by the research should be used to justify risks to participants

Two benchmarks unique to developing countries.

1. the risk-benefit ratio for individuals must be favorable in the context in which they live.

2. the risk-benefit ratio for the community should be favorable (look at benefits from collaborative partnership, social value, respect for study population).

“Minimal Risk Research”

Minimal risk research

Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

Minimal risk research

Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Minimal risk research

Collection of data from voice, video, digital, or image recordings made for research purposes.

Minimal risk research

Clinical studies of drugs and medical devices only when condition a or b is met:

a. **Research on drugs for which an investigational new drug application is not required (exception: research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product)**

b. **Research on medical devices for which the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.**

Minimal risk research

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

a. from healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

b. from other adults and children2, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

Minimal risk research

Prospective collection of biological specimens for research purposes by noninvasive means.

Examples:

a. hair and nail clippings in a nondisfiguring manner;
b. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
c. permanent teeth if routine patient care indicates a need for extraction;
d. excreta and external secretions (including sweat);
e. uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
f. placenta removed at delivery;
g. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
h. supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
i. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
j. sputum collected after saline mist nebulization.

Minimal risk research

Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples:

a. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy;
b. weighing or testing sensory acuity;
c. magnetic resonance imaging;
d. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
e. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

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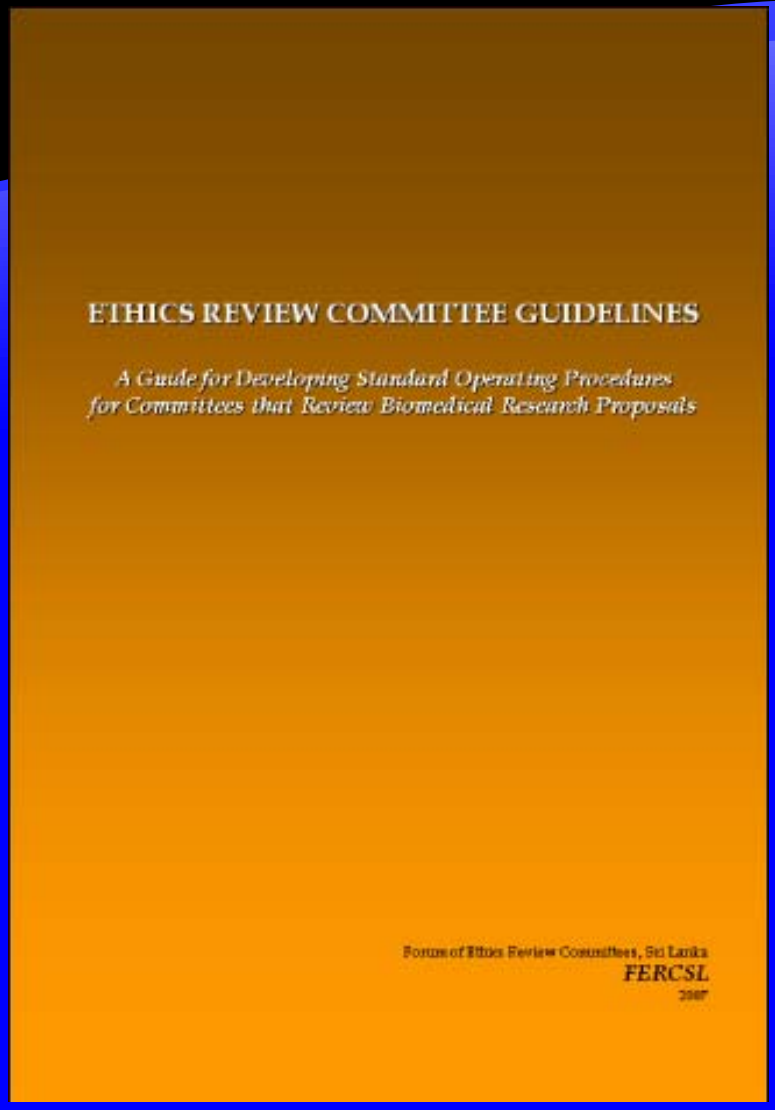
ETHICS REVIEW COMMITTEE GUIDELINES
A Guide for Developing Standard Operating Procedures for Committees that Review Biomedical Research Proposals
Forum of Ethics Review Committees, Sri Lanka
FERCSL
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Chairperson's Review